IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MYLAN PHARMACEUTICALS INC.,	Civil Action No. 2:14 cv-02094-ES-MAH
	Hon. Esther Salas, U.S.D.J.
Plaintiff,	Hon. Michael A. Hammer, U.S.M.J.
v.	
CELGENE CORPORATION,	JURY TRIAL DEMANDED
Defendant.	

JOINT DISCOVERY PLAN

1. Factual Description of the Case

(a) Plaintiff's Description of the Case

Plaintiff Mylan Pharmaceuticals, Inc. ("Mylan") sues defendant Celgene Corporation ("Celgene') for violations of federal and state antitrust law. Celgene has unlawfully maintained monopolies over its two "lead" products—Thalomid and Revlimid—by preventing lower-priced generic competition from entering the market.

Thalomid and Revlimid treat critically ill patients. Thalomid (the branded version of thalidomide) is indicated for the treatment of debilitating and disfiguring lesions associated with erythema nodosum leprosum ("ENL"), a complication of Hansen's Disease, commonly known as leprosy. It is also indicated for the treatment of newly diagnosed multiple myeloma patients in combination with the pharmaceutical dexamethasone. Revlimid (the branded version of lenalidomide) is indicated for the treatment of a subset of myelodysplastic syndromes ("MDS")—a group of disorders caused by poorly formed or dysfunctional blood cells.

Access to these drugs is restricted. Because of safety concerns, the FDA has imposed restrictions on the distribution of both Thalomid and Revlimid. For both drugs, the FDA conditioned Celgene's approval on the establishment of a risk management program, including a Risk Evaluation and Mitigation Strategies ("REMS") program, to ensure that there were appropriate safeguards for the use and distribution of these drugs. To meet these requirements, Celgene developed a restricted distribution program for Thalomid, known as the System for Thalidomide Education and Prescribing Safety ("S.T.E.P.S."). Similarly, for Revlimid, Celgene developed a REMS program called RevAssist. In the legislation mandating the implementation of REMS for certain drugs, including Thalomid and Revlimid, Congress made clear that such programs were *not* to be used by branded drug makers as a tool to keep generic competitors out of the market. *See* Food Drug and Cosmetic Act §505-1(f)(8) (21 U.S.C. § 355-1).

Under the Hatch-Waxman Act (a statutory scheme designed, in part, to encourage generic competition), a generic drug manufacturer can seek FDA approval for a generic version of a branded drug product by filing an Abbreviated New Drug Application ("ANDA"). Through the ANDA filing, a generic drug maker must demonstrate bioequivalence to the reference listed branded drug ("RLD") (i.e., the branded drug to which the generic will be bioequivalent). Ordinarily, a generic manufacturer can obtain the necessary samples of the RLD for bioequivalence testing through normal distribution channels (*i.e.*, a wholesaler) simply by purchasing a sufficient quantity of the drug at market price. However, a generic firm like Mylan may not do so for Thalomid and Revlimid because of the respective REMS programs for these drugs.

Celgene has used its REMS programs as a pretext to prevent Mylan from acquiring the necessary samples to conduct bioequivalence studies, even after the FDA determined that

Mylan's safety protocols were acceptable to conduct those studies. Celgene has refused, on numerous occasions and using a variety of tactics, to provide Mylan with samples of Thalomid and Revlimid necessary to perform bioequivalence studies. The effect of Celgene's conduct is that Mylan has not been able to bring generic versions of Thalomid or Revlimid to market.

Celgene claims that it remains willing to provide Mylan with samples, but that Mylan refuses to provide "even basic information" regarding its safety procedures. That is false. Mylan's 380-paragraph Complaint details a tortured history of Mylan's attempts—over the course of several years—to secure limited samples of these products from Celgene. At every turn, Mylan acceded to Celgene's demands for irrelevant and overbroad information—and agreed to indemnification even though Mylan never sought to commercially sell the product—until it became clear that further engagement with Celgene was fruitless.

While Celgene claims that it has provided Thalomid and Revlimid samples to other generics when they meet Celgene's conditions, the evidence is to the contrary. For example, in 2008, Celgene was sued by another generic company under the antitrust laws alleging the exact same conduct that Mylan is alleging here with respect to Thalomid. Compl. at 8. After Celgene's motion to dismiss was denied, the parties settled the case. *Id.* To the extent that Celgene provided samples as part of that settlement, it was due to the risk of treble damages under the antitrust laws, not a sudden resolution of its pre-textual "safety" concerns. In addition, Celgene was accused by another generic in 2009 of repeating the same conduct with respect to Revlimid. *Id.* Finally, Celgene's efforts to block generic competition to its two lead products has even prompted an antitrust investigation by the Federal Trade Commission. *Id.*

While Celgene claims that its "motion describes the six irreparable defects meriting dismissal," Mylan's antitrust claims will survive a motion to dismiss. Mylan will present a full

response to Celgene's motion in its opposition, but it is critical to note that less than a year ago, Judge Noel Hillman in the District of New Jersey ruled from the bench on an almost identical issue. *See Actelion Pharms. Ltd. v. Apotex, Inc.*, No. 1:12-cv-5743 (D.N.J. 2013). In Actelion, a brand pharmaceutical manufacturer, refused to provide samples of its restricted distribution drugs to generic manufacturers. The generic manufacturers filed counterclaims, akin to the claims at issue here, alleging that Actelion had violated federal and state antitrust laws by denying the generic manufacturers the ability to purchase samples for bioequivalence testing, thereby unlawfully preventing them from filing ANDAs and entering the market.

On October 17, 2013, following oral argument, Judge Hillman ruled from the bench, denying Actelion's motion for judgment on the pleadings and denying its motion to dismiss the generics' antitrust counterclaims. *See* Tr. at 115-7, *Actelion Pharms. Ltd. v. Apotex, Inc.*, No. 12-cv-5743-NLH (D.N.J. Oct. 17, 2013) ("I find that the determination of whether plaintiff's refusal to deal here, sell samples, amounts to protected and lawful conduct *should await full discovery*, and I will allow the case to proceed that way.") (emphasis added). Mylan similarly brings this suit alleging that Celgene has violated both Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, as well as the New Jersey Antitrust Act Section 56, N.J. Stat. Ann. §§ 56:9-3 and 56:9-4. Additionally, Mylan alleges that that the defendant has engaged in unfair competition and has tortiously interfered with Mylan's economic advantage, in violation of the common law of the State of New Jersey. Mylan seeks damages, a preliminary and permanent injunction and a declaratory judgment.

Mylan filed its Complaint on April 3, 2014. On April 23, 2014, Magistrate Judge Hammer ordered an Initial Scheduling Conference on June 3, 2014.

(b) Defendant's Description of the Case

Although it has no legal obligation to do so, Celgene has been, and remains, willing to sell Thalomid® and Revlimid® samples to Mylan. All Mylan needs to do is satisfy Celgene's safety, regulatory, business reputation, and liability concerns. When other generic companies have satisfied those concerns, Celgene has agreed to sell the samples Mylan seeks. Nonetheless, Mylan insists that it is special and should not be required to do what those other generic companies have done. Mylan has thus refused to provide Celgene with even basic information about Mylan's history of handling dangerous or hazardous pharmaceuticals and chemicals or its ability to indemnify Celgene for the risks its use of these teratogenic drugs entail.

Instead, Mylan asserts that it needs access to Celgene's drugs in order to seek FDA approval for its own generic versions to be sold in competition with Celgene; that Celgene is a "monopolist" as to the sale of its own drugs; and that Celgene is therefore required by the antitrust laws to sell its products to Mylan on terms Mylan finds reasonable. The principal flaw in Mylan's theory is this: "[A] complaint . . . which takes the form 'X is a monopolist, [and] X didn't help its competitors enter the market so that they could challenge its monopoly . . .' does not state a claim under [the Sherman Act]. The reason is because the antitrust laws do not impose that kind of affirmative duty . . . ." *Goldwasser v. Ameritech Corp.*, 222 F.3d 390, 400 (7th Cir. 2000).

Celgene has a genuine need for the information. Though Mylan's complaint carefully omits any explanation of why the FDA has restricted the distribution of these two life-extending drugs, their risks are well known. The FDA-approved label for Thalomid® warns that "[e]ven a single dose . . . can cause severe birth defects." Likewise, Revlimid®'s label cautions that "it may cause birth defects or embryo-fetal death." The risks to fetuses, in particular, demonstrates

why Mylan's assurances regarding indemnification are not sufficient. An adverse event (whether during a bioequivalency study or after a generic approval) would expose Celgene to reputational harm and the potential loss of its entire market if the FDA forces withdrawal of the drugs. Moreover, some states have held that liability may be imposed on the branded seller of a given drug for injuries caused by a commercialized generic version, even though it was not sold by the brand. Celgene would thus be exposed to up to *twenty years* of potential products liability suits, given tolling of the statute of limitations during a victim's minority.

Mylan's Complaint ignores a second, and equally fatal, fact. Celgene holds numerous patents covering the basic Revlimid® compound; composition of matter and method of use patents for Thalomid® and Revlimid®; and patents on Celgene's Risk Evaluation and Mitigation Systems for distributing both drugs. Celgene thus has a right to exclude Mylan from its inventions, a right that the antitrust laws respect. 35 U.S.C. § 154; *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1328 (Fed. Cir. 2000).

The first and critical legal issue will be whether such a complaint can withstand a motion to dismiss. It cannot.

Celgene's pending motion to dismiss describes the six irreparable defects meriting dismissal. *First*, the Supreme Court has long held that "the [Sherman] act does not restrict the long recognized right of trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal. And, of course, he may announce in advance the circumstances under which he will refuse to sell." *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919). Mylan has alleged neither prior dealings with Celgene nor irrational profit sacrifice, both of which are necessary to find an antitrust duty to deal. *Second*, Celgene cannot conspire with its distribution agents, and Mylan has not alleged any

harm from such alleged conspiracy separate and apart from the FDA's REMS mandate. *Third*, all Thalomid® counts are barred by the statute of limitations because Celgene's last refusal to sell that drug was alleged in the Complaint to have occurred in 2009. *Fourth*, Mylan's product market allegations provide no facts concerning the multiple other drugs indicated for treatment of the same conditions as Thalomid® or Revlimid®. *Fifth*, Celgene's patents prevent Mylan from showing injury to *lawful* competition. *Finally*, Mylan's state law claims fall with its failed antitrust theories.

At bottom, Mylan's claims rest on a false premise: That because the Hatch-Waxman Act gives certain advantages to generic competitors, Celgene was obligated to act in whatever manner would maximize that benefit. Not so. "[A]ffirmative duties to help one's competitors . . . do not exist under the unadorned antitrust laws." *Goldwasser v. Ameritech Corp.*, 222 F.3d 390, 399-400 (7th Cir. 2000).

2. Settlement Discussions

No settlement discussions have taken place to date.

3. Discovery:

(a) Scope:

(1) Plaintiff's Position

While district courts have discretion to impose or deny a stay of discovery under Fed. R. Civ. P. 26, 42. Celgene's entire argument in support of a stay is based on its belief in the righteousness of its legal position. Celgene's hopes, suppositions, and aspirations have already been rejected by this Court in a strikingly similar matter. *See Actelion Pharms. Ltd. v. Apotex, Inc.*, No. 1:12-cv-5743 (D.N.J. 2013); *see also Lannett Co. v. Celgene Corp.*, No. 2:08-cv-03920 (E.D. Pa. 2008) (refusing to dismiss generic's complaint against Celgene based on identical

conduct with respect to Thalomid). Mylan's 380-paragraph complaint details Celgene's anticompetitive conduct relating to its scheme to misuse REMS to prevent generic competition to Thalomid and Revlimid, just as was alleged in parallel fashion in *Actelion*. In that case, in allowing plaintiffs to proceed to discovery, Judge Hillman stated:

> When I read *Trinko* and *Aspen Highlands*, I look at those cases through the lens of the case now almost a hundred years old, *Colgate* and *Otter Tail*, it suggests to me that the proper application of the antitrust laws is almost always a fact-specific one and, indeed, an industry-specific one. In essence, I simply can't find that or hold that *Trinko* supplies the simple answer to the issue that's been presented to this Court. The FDA is not the FCC. It's a different environment. . . And it's clear to me that the FDA does not have the regulatory power to compel samples and that there is no other potential remedy to a defendant suffering anticompetitive conduct in that regulatory scheme. . . The question, sole question, is whether or not discovery should proceed to allow the defendants to flesh out those claims, and I will allow them to do so. I find that [generics' counterclaims] are sufficiently pled under the Twombly/Iqbal standard in the context of this case.

See Tr. at 115-7, *Actelion Pharms. Ltd. v. Apotex, Inc.*, No. 12-cv-5743-NLH (D.N.J. Oct. 17, 2013).

Celgene cannot argue that discovery, as proposed by Mylan, will cause it prejudice, nor has it established that any efficiency would be served by a discovery stay. Rather, a discovery stay would likely result in a significant delay of adjudication of Mylan's claims, which include requests for injunctive relief to get samples of the products to begin bioequivalence testing. As such, Mylan expects to require fact and/or expert discovery on all issues raised in the Complaint and any Answer and/or Counterclaims, including but not limited to: Thalomid, Revlimid, generic thalidomide and generic lenalidomide (Relevant Products); R&D of Relevant Products; FDA approval of Relevant Products; promotion of Relevant Products; economic and marketing information regarding Relevant Products, such as market-share, revenue and sales, and/or profit projections; product market; effects of generic entry; REMS programs; the provision of Relevant

Products by Celgene to third parties; Mylan's efforts to secure samples of Relevant Products; agreements, negotiations and decisions between Celgene and third parties regarding Relevant Products and REMS programs; correspondence between Celgene and the FDA or other government agencies regarding Relevant Products and REMS programs; any FTC investigation or investigation by any other agency, including state Attorneys General offices, into Celgene's conduct as it relates to Relevant Products or REMS programs; other litigations in which Celgene has participated, involving similar or identical facts; citizen petitions to the FDA regarding Celgene's conduct as it relates to Relevant Products and REMS programs. The foregoing list is not exhaustive and without prejudice to Mylan's right to designate additional topics for discovery, which is expressly reserved.

With regard to the relevant FTC submissions, Celgene ignores that Mylan's proposal is not a one-way street. Mylan has agreed to produce documents it produced to the FTC as part of that investigation. Certainly Mylan's production is substantially smaller than Celgene's production as Celgene is the target of that investigation. But nonetheless the burden on Celgene is not great to reproduce these materials. Celgene's argument that Mylan has "no basis to assume that all materials relevant to the FTC and related State Attorneys General investigations of Celgene's conduct with respect to the Thalomid and Revlimid would necessarily be relevant to the conduct alleged in Mylan's Complaint" is meritless. The FTC and State Attorney General were/are investigating Celgene for monopolization of Thalomid and Revlimid by way of abusing REMS. The FTC, in particular, is the federal enforcer of the antitrust laws, and thus its investigation would seek documents regarding the anticompetitive conduct at issue (i.e., Celgene's REMS abuses), conduct regarding potential entrants into the marketplace (e.g., Mylan and other possible entrants), competition in the marketplace (i.e., to evaluate fact-driven relevant

market issues), and other issues that would be involved in an FTC investigation of anticompetitive conduct that will parallel the issues relevant to discovery in the present action. Celgene provides no basis for distinguishing between the two matters.

Further, while Celgene's statute of limitations arguments with respect to Thalomid will fail, they do not have any bearing on potential discovery because the information sought by Mylan concerning Thalomid is otherwise relevant to the case. *See Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 352 (1978) ("[I]t is proper to deny discovery of matter that is relevant only . . . to events that occurred before an applicable limitations period, *unless the information sought is otherwise relevant to issues in the case*."). Mylan has alleged that Celgene's conduct with respect to Thalomid and Revlimid are pages of the same "playbook of obstructing its generic competitors by gaming the regulatory system." Compl. ¶8. Therefore, in order to show that Celgene's conduct is part of the same scheme, it would need discovery as it relates to both Thalomid and Revlimid.

(2) Defendant's Position

The scope of discovery will be affected profoundly by the Court's decision on Celgene's pending motion to dismiss all of Mylan's claims, filed on May 25, 2014. If that motion is successful in whole or even in significant part, the scope—and cost—of discovery will be directly affected. If the motion is granted, the case is over. If even one of the principal claims is dismissed—such as the Thalomid® claims based on the statute of limitations—the effect on discovery will be dramatic.[1]

[1] *See, e.g., Weisman v. Mediq, Inc.*, No. 95-1831, 1995 U.S. Dist. LEXIS 5900, at *5 (E.D. Pa. May 3, 1995) ("[A] stay is proper where the likelihood that such motion [to dismiss] may result in a narrowing or outright elimination of discovery outweighs the likely harm to be produced by the delay."); *see also Chudasama v. Mazda Motor Corp.*, 123 F.3d 1353, 1367-68 (11th Cir. 1997) ("Facial challenges to the legal sufficiency of a claim" should ordinarily "be

This is one of the reasons that this Court's Local Rules envision that a Rule 16 conference will not take place until a defendant files an answer. *See* L.Civ.R. 16.1(a)(1) ("The initial conference shall be scheduled within 60 days of filing *of an initial answer*." (emphasis added)). And that is also a customary practice of this Court. *See In re Fleetboston Fin. Corp. Sec. Litig.*, No. 02-4561, 2007 BL 158149, at *1-2 (D.N.J. Nov. 28, 2007) (detailing procedural history of case by noting that motion to dismiss preceded answer, which in turn preceded scheduling conference); *see also Bishop-Melvin v. First Am. Acceptance Co.*, No. 12-31, 2012 BL 212155, at *7 (D.N.J. Aug. 20, 2012) ("The Court acknowledges that a Rule 16 Conference was set because an Answer was filed.").

This practice makes eminent sense, as *Fleetboston* and *Bishop-Melvin* demonstrate. In *Fleetboston*, the motion to dismiss was granted in part, streamlining the case and avoiding the cost of unnecessary discovery. In *Bishop-Melvin*, the case settled. And even if neither of these events come to pass, the filing of an answer shows what claims and defenses are genuinely in dispute—defining the appropriate scope of discovery under Rule 26(b)(1). This information is necessary to inform both the Court and counsel regarding reasonable discovery deadlines as well as other case management topics addressed at a Rule 16 conference.

Celgene further submits that Mylan has identified topics that are not relevant to Mylan's claims, as defined by Mylan's current complaint. For example, Mylan does not allege that Celgene's marketing and promotion of the Named Products violated the antitrust laws, or constituted tortious conduct in violation of the common law. Likewise, Mylan provides no basis to assume that all materials relevant to the FTC and related State Attorneys General

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resolved before discovery begins" to avoid "unnecessary costs to the litigants and to the court system.").

investigations of Celgene's conduct with respect to the Named Products would necessarily be relevant to the conduct alleged in Mylan's Complaint.

Celgene submits that discovery should be temporally limited. Mylan apparently will seek information regarding facts and events far outside the statute of limitations. Because the longest statute of limitations applicable to Mylan's claims is six years, the presumptive discovery period should be April 4, 2008 to the present, except where Mylan can show that earlier materials are otherwise relevant to the Parties' claims and defenses. *See Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 352 (1978) ("[I]t is proper to deny discovery of matter that is relevant only . . . to events that occurred before an applicable limitations period, unless the information sought is otherwise relevant to issues in the case."). With respect to earlier materials, the Court should balance the likelihood of unearthing relevant information against the burden of locating and furnishing that information. *See Miller v. Hygrade Food Prods. Corp.*, 89 F. Supp. 2d 643, 657 (E.D. Pa. 2000).

While Mylan contends that Judge Hillman's decision denying Actelion's motion to dismiss in *Actelion Pharms. Ltd. v. Apotex, Inc.*, No. 1:12-cv-5743 (D.N.J. 2013) should resolve the issues in this case, the Actelion court did precisely what Celgene recommends here. Judge Hillman carefully considered the motion to dismiss *before* discovery commenced. *See* Mem. Op. & Order, *Actelion Pharms. Ltd. v. Apotex, Inc.*, No. 1:12-cv-5743 (D.N.J. 2013) (Doc. 88) at 11 (Sept. 6, 2013) (granting motion to stay discovery recognizing that "the potential cost of discovery establishes a specific and substantial risk of harm" that resolution of the motion to dismiss could avoid). Only after concluding that the complaint might state a claim did the Court permit discovery to proceed. Actelion had important differences from this case, and lacked the

additional grounds for dismissal Celgene has raised here, but the Court's procedure was appropriate, and exactly what Celgene's proposed schedule would allow here.

(b) Case Schedule

The Parties have not reached agreement concerning the schedule for this case. Their proposals are set forth below, followed by a brief explanation of their positions. Further, Mylan proposed to Celgene (and provided draft copies on May 19th) of a proposed Discovery Confidentiality Order and proposed Electronically Stored Information Protocol. Celgene proposes submission of those documents following resolution of the motion to dismiss. Mylan submits those documents as EXHIBITS A and B for the Court's consideration:

Event	Plaintiffs' Proposal	Defendant's Proposal
Defendant's Answer		14 days following Resolution of Motion to Dismiss ("RMTD"). *See* Fed. R. Civ. P. 12(a)(4)(A)
Deadline for submission of proposed Discovery Confidentiality Order	June 2, 2014	20 days following RMTD
Deadline for submission of proposed Electronically Stored Information Protocol	June 2, 2014	20 days following RMTD
Initial Scheduling Conference	June 3, 2014	20 days following RMTD
Deadline for substantial completion of production of Stage 1 Discovery Materials	August 4, 2014	N/A
Rule 26(a)(1) Initial Disclosures to be served	August 4, 2014	20 days following RMTD

All parties serve first request for production of documents	September 3, 2014	20 days following RMTD Responses due no earlier than 20 days after Court enters Discovery Confidentiality Order
Deadline to amend and/or add parties without leave of Court	October 1, 2014	June 16, 2014. *See* Fed. R. Civ. P. 15(a)(1)
Deadline for substantial completion of production of documents responsive to all Stage 2 requests for production served on or before August 3, 2014	December 3, 2014	N/A
Deadline to amend and/or add parties with leave of Court	January 15, 2015	
Fact discovery closes; all discovery requests must be served to be answerable by this date.	March 3, 2015	12 months following RMTD
Deadline for the party with the burden of proof on an issue serves its expert report(s) on that issue, with the dates for expert depositions to be providing at the time of filing.	April 3, 2015	2 months following close of fact discovery
Deadline for the parties to serve responsive expert reports, with the dates for expert depositions to be provided at the time of filing	May 4, 2015	1 ½ months following submission of opening expert reports
Deadline for the parties to serve rebuttal expert reports, with the dates for expert depositions to be provided at the time of filing	May 25, 2015	1 month following submission of responsive expert reports
Expert discovery closes	June 22, 2015	6 months following close of fact discovery
Last date to file Rule 56 dispositive motions	July 15, 2015	2 months following close of expert discovery
Final Pretrial Conference	At the Court's convenience, in or about September 2015	At the Court's convenience, 4 months following date for dispositive motions

Trial	At the Court's convenience, in or about October 2015	At the Court's convenience, at least one month following Final Pretrial Conference

(1) Plaintiffs Position:

Discovery will be conducted in phases, as follows:

Mylan proposed the following categories of documents, which are more accessible than other materials and capable of production without significant further collection and review effort, and which may help to focus other discovery efforts, to be produced on an expedited basis ("Stage 1").

Mylan disagrees that the schedule proposed by Celgene is similar in substance to Mylan's proposal. Below, Celgene proposes to delay discovery at *every* stage[2] without providing a single specific good faith basis for why it needs more time, other than a general assertion that Celgene's "deadlines are more suited for a complicated antitrust case." Further, Celgene's assertion that it would be required to produce its Stage 1 documents within *one month (two months, as now proposed by Mylan)*, while permitting Mylan over nine months to respond to produce its own documents is plain wrong. Mylan has requested certain easily accessible documents from Celgene, but at the same time proposed to turn over its own FTC submissions by August 3, 2014.

Here in this matter, the Court should find materials previously turned over to a government body or third parties discoverable so long as they are relevant, non-privileged, and not produced in response to a grand jury subpoena under Rule 6(e).

[2] While Mylan proposes a nine month fact discovery period, Celgene proposes twelve; while Mylan proposes a three-and-a-half month expert discovery period, Celgene proposes six.

A. Automatic Production by Defendants

i) Materials Produced to the Federal Trade Commission: All non-privileged materials submitted to the Federal Trade Commission, in response to subpoenas or voluntarily, as part of the Federal Trade Commission's investigation into Celgene's conduct as it relates to Thalomid and Revlimid and/or REMS programs. Any deposition or investigational hearing transcripts produced as part of this investigation should also be produced.

ii) Materials Produced to State Attorneys General: All non-privileged materials submitted to the Connecticut Attorney General (or any other state Attorney General), in response to requests or voluntarily, as part of any investigation into Celgene's conduct as it relates to Thalomid and Revlimid and/or REMS programs.

iii) Materials Produced to the Food and Drug Administration: All non-privileged materials produced to the Food and Drug Administration, either by request or voluntarily, in connection with Celgene's Citizen Petition in September 2007 (Docket No. FDA-2007-P-0113) or in connection with Dr. Reddy's Laboratories, Inc.'s Citizen Petition in June 2008 (Docket No. FDA-2009-P-0266).

iv) Lannett Litigation Materials: All non-privileged materials produced by Celgene as part of the lawsuit filed by Lannett Company, Inc. against Celgene in 2008 (Lannett Company, Inc. v Celgene Corporation, No. 08-3920) (E.D. Pa. filed Aug. 15, 2008).

B. Automatic Production by Mylan:

i) Materials Produced to the FTC: All non-privileged documents submitted to the Federal Trade Commission, in response to subpoenas or

voluntarily, as part of the Federal Trade Commission's investigation into Celgene's conduct as it relates to Thalomid and Revlimid and/or REMS programs. Depositions transcripts produced as part of this investigation will also be produced.

Parties will have substantially completed production of these Stage 1 materials by August 3, 2014.

In Stage 2, Mylan proposes that all remaining discovery will proceed according to the schedule set forth above. That schedule provides for, among other things, the substantial completion of the production of documents responsive to all requests for production served on or before September 3, 2014 by no later than December 3, 2014.

Mylan submits that the Court should adopt the following standard for the timing of both Stage 1 and Stage 2 document productions: Subject to any obligation of the parties to supplement discovery under the Federal Rules or the Rules of this Court, any documents produced by a party after the respective foregoing scheduled dates applicable to those documents (a) must not exceed an insubstantial number of documents (i.e., no more than ten (10) percent), and (b) could not otherwise have been discovered or produced earlier in this case, as demonstrated to the Court by the producing party upon an objection to such production submitted to the Court by the non-producing party. The producing party shall not be permitted to use or otherwise rely upon for any purpose whatsoever in this case any documents sought to be produced after the respective foregoing scheduled dates applicable to those documents that exceed an insubstantial number of documents, absent a showing to the Court of good cause for such belated production and lack of prejudice to adverse parties. This standard is without prejudice to the non-producing party's ability to request different and/or additional relief based upon such conduct by the producing party.

(2) Defendant's Position:

The schedule proposed by Celgene is similar in substance to Mylan's proposal. Mylan proposes a nine month fact discovery period; Celgene proposes twelve. Mylan proposes a three-and-a-half month expert discovery period; Celgene proposes six. Celgene believes its deadlines are more suited for a complicated antitrust case.

Where the schedules differ is in Mylan's rush to commence full discovery, with all of its onus and cost, well before the motion to dismiss is even fully briefed. As shown above, that is contrary to this District's local rules and customary practice. *See* L.Civ.R. 16.1(a)(1). *See In re Fleetboston Fin. Corp. Sec. Litig.*, No. 02-4561, 2007 BL 158149, at *1-2 (D.N.J. Nov. 28, 2007); *Bishop-Melvin v. First Am. Acceptance Co.*, No. 12-31, 2012 BL 212155, at *7 (D.N.J. Aug. 20, 2012).

Particularly egregious is Mylan's proposal for what it calls "bifurcated" discovery. It would have Celgene produce the vast majority of its documents—including the 379,000 documents spanning more than 2,400,000 pages that Celgene produced to the FTC, whether remotely relevant to this case or not—originally within *one month* and later revised to two months, while permitting Mylan over nine months to respond to produce its own documents. All materials produced to the FTC are confidential by statute, so there is no need to designate such materials under a discovery confidentiality order. Moreover, because Mylan seeks this automatic disclosure without having issued a single document request, Celgene cannot determine whether all of the documents produced to the FTC investigation are even relevant to Mylan's claims. Mylan claims that production of these materials would not entail significant further review effort, but that is false. Celgene estimates that re-reviewing the 379,000 FTC documents for relevance and confidentiality alone will take 7,500 attorney hours to complete. The cost for this review

and production is estimated at more than $500,000. Even if Celgene were required to undertake such a significant cost and burden before its motion to dismiss is resolved, this Court should not indulge Mylan's fantasy that such an effort can be completed in the next 60 days.

(c) Discovery Limits

(1) Areas of Agreement

The Parties agree that limitations in the Federal Rules of Civil Procedure should govern Interrogatories and Requests for Production. The Parties have not, however, reached agreement concerning the appropriate limitations for depositions. Their proposals follow:

(2) Plaintiff's Position

A. Both Parties may take a total of twenty (20) fact depositions. Notwithstanding the foregoing, the parties reserve the right to seek leave of the Court to increase the number of fact depositions to be taken.

B. Each Rule 30(b)(6) deposition counts against the per-side fact deposition cap. Any Rule 30(b)(6) deposition of a named party noticed by Plaintiff or Defendant counts as one (1) deposition no matter the number of witnesses designated to testify, unless the deposition exceeds 7 hours. In the event that a Rule 30(b)(6) deposition exceeds 7 hours, the additional hours shall count as an additional deposition or the pro rata portion of an additional deposition (e.g., if a Rule 30(b)(6) deposition lasts 14 hours, it shall count as 2 depositions out of the 20 party depositions allocated per party; if a Rule 30(b)(6) deposition lasts 10.5 hours, it shall count as 1½ depositions out of the 20 party depositions allocated per party). Subject to the per-party fact deposition cap, the parties are not precluded from seeking the deposition of a Rule 30(b)(6) designee in their individual capacity.

C. A non-party deposition will not count as one deposition against the per-party fact deposition cap. Mylan proposes no cap on non-party depositions as it is extremely difficult at this time and prior to discovery to determine how many such parties (e.g., other generic market participants, other purported branded competitors, distributors) may be required to be deposed. Mylan would be willing to agree to a 20 deposition cap on non-parties while providing that the parties reserve the right to seek leave of the Court to increase the number of non-party depositions to be taken.

(3) Defendant's Position

A. The provisions of Federal Rule of Civil Procedure 30 and the Advisory Committee Notes explaining that Rule should govern depositions. Mylan's proposal does far more than simply double the number of fact depositions allowed by the rules. It would make the total number boundless, by providing that third party depositions do not count against the total. Mylan makes no attempt to show good cause for such a change.

(d) Special Discovery Procedures:

(1) The parties have agreed that drafts of expert reports or declarations and notes, written communications, and other types of preliminary work created or generated by or for experts or their staff (unless such notes are generated while testifying) are exempt from discovery. Communications between and among (a) experts, including their staff, and outside counsel, (b) experts, including their staff, and other experts or consultants and their respective staff, and/or (c) experts and their respective staff shall not be discoverable unless the expert specifically relied upon any such communications as a basis for any of his or her ultimate opinions or reports. Suggestions from outside counsel regarding revisions to the form of the

expert's report or additional support for the expert's ultimate opinions are examples of communications that are protected from discovery under this Order.

(2) The parties anticipate that a Discovery Confidentiality Order governing the treatment of confidential information will be required and that the Court will be asked to adopt it. Mylan submits concurrently with this discovery plan a proposed Discovery Confidentiality Order for the Court's consideration. Celgene objects to Mylan's unilateral submission of its proposed Confidentiality Order. Celgene has proposed a schedule for negotiating a confidentiality order as contemplated by this Court's rules.

(3) The parties are prepared to engage in reasonable electronic discovery in response to discovery requests. Mylan submits concurrently with this discovery plan a proposed ESI agreement for the Court's consideration. Celgene objects to Mylan's unilateral submission of its proposed ESI agreement. Celgene has proposed a schedule for negotiating an ESI agreement as contemplated by this Court's rules.

(4) The Parties agree that, except where infeasible, they shall serve all pleadings, discovery requests, and discovery responses by electronic mail. Service of discovery requests will be deemed to have been made on the day after the electronic mail is sent. Service of pleadings and discovery will be deemed to have been made on the day electronic mail is sent by the sender, based on the time zone of the District Court.

(e) Jury Trial

In its Complaint, Mylan demanded a trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure.

(f) Trial Date

To be set by the Court, at its convenience in or about October 2015 per Mylan's proposed schedule, or in accordance with the case schedule set by Celgene.

4. Anticipated Discovery Problems

No discovery problems are anticipated at this time.

5. Special Discovery Needs

The parties anticipate the need to videotape many, if not all, depositions.

6. Expert Testimony

The Parties expect the expert testimony will be necessary and propose the schedules for expert report submissions and responses set forth above.

7. Alternative Dispute Resolution Procedures

Parties are willing to engage in alternative dispute resolution procedures. If it appears that voluntary arbitration (pursuant to L. Civ. R. 201.1 or otherwise), mediation (pursuant to L. Civ. R. 301.1 or otherwise), or appointment of a special master would help to facilitate resolution or discussion, both parties would be amenable submitting to such procedures at an appropriate point in time.

8. Bifurcation

The parties do not believe this case is appropriate for bifurcation.

9. Trial Conducted by Magistrate Judge

The parties do not consent to the trial being conducted by a Magistrate Judge.

Dated: June 2, 2014

/s/ Arnold B. Calmann
Arnold B. Calmann
(abc@saiber.com)
Jakob B. Halpern
(jbh@saiber.com)
SAIBER LLC
One Gateway Center
10th Floor, Suite 1000
Newark, NJ 07102-5311

Of counsel:

Seth C. Silber (ssilber@wsgr.com)
Jonathan R. Lutinski (jlutinski@wsgr.com)
Valentina V. Rucker (vrucker@wsgr.com)
Roisin Comerford (rcomerford@wsgr.com)
WILSON SONSINI GOODRICH & ROSATI
1700 K St N.W., 5th Floor
Washington, DC 20006

ATTORNEYS FOR PLAINTIFFS
MYLAN PHARMACEUTICALS INC.

/s/ Daniel R. Guadalupe
Daniel R. Guadalupe
(drguadalupe@nmmlaw.com)
Norris McLaughlin & Marcus, P.A.
721 Route 202/206, Suite 200
P.O. Box 5933
Bridgewater, NJ 08807

Of counsel:

Kevin D. McDonald (kdmcdonald@jonesday.com)
Phillip A. Proger (paproger@jonesday.com)
John M. Majoras (jmmajoras@jonesday.com)
Rosanna K. McCalips (rkmccalips@jonesday.com)
Mark R. Lentz (mrlentz@jonesday.com)
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001

ATTORNEYS FOR DEFENDANT
CELGENE CORPORATION

EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MYLAN PHARMACEUTICALS INC. Plaintiff, vs. CELGENE CORPORATION, Defendant.	Civil Action No.: 14-2094-ES-MAH **STIPULATED DISCOVERY CONFIDENTIALITY ORDER** *DOCUMENT FILED ELECTRONICALLY*

In the interests of (i) promoting an efficient and prompt resolution of this Action; (ii) facilitating discovery by Plaintiff Mylan and Defendant Celgene ("Parties") litigating this Action; and (iii) protecting the Parties' and non-parties' Confidential Information and Attorneys' Eyes Only Information from improper disclosure or use, the Parties have stipulated to the provisions set forth below and, in support thereof, have submitted the Declarations of [NAME] and [NAME] explaining why Parties believe the entry of this Stipulated Discovery Confidentiality Order ("Order") is necessary. Upon good cause shown, *see Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786-87 & n.17 (3d Cir. 1994); *Cippollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1122 (3d Cir. 1986), the Court, pursuant to Fed. R. Civ. P. 26(c)(1)(G) and Local Civil Rule 5.3, ORDERS as follows:

A. DEFINITIONS

1. As used in this Order:

(a) "**Action**" means the above-captioned action pending in this Court, including any pretrial, trial, post-trial, or appellate proceedings.

(b) "**Attorneys' Eyes Only Information**" shall have the meaning specified in Paragraph 3.

(c) "**Confidential Information**" shall mean any information, document, or thing, or portion of any document or thing: (a) that contains trade secrets, competitively sensitive technical, marketing, financial, sales or other confidential business information, or (b) that contains private or confidential personal information, or (c) that contains information received in confidence from third parties, or (d) which the producing party otherwise believes in good faith to be entitled to protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure and Local Civil Rule 5.3. Confidential Information shall include, but not be limited to, the New Drug Application Nos. 02-0785, 02-1430 and 02-1880, including all supplements, updates, amendments and revisions thereto. Confidential Information shall apply to all information, documents and things within the scope of discovery that are designated as containing or comprising Confidential Information, including, without limitation, documents and things responsive to requests for production of documents and things under Fed. R. Civ. P. 34; information produced by other persons that the producing or designating party is under an obligation to maintain in confidence; responses to written interrogatories under Fed. R. Civ. P. 33; responses to requests for admission under Fed. R. Civ. P. 36 or other discovery requests; testimony adduced at depositions upon oral examination or upon written questions pursuant to Fed. R. Civ. P. 30 and 31, hearings or trial. The information contained therein and all copies, abstracts, excerpts, analyses or other writings that contain, reflect, reveal, suggest or otherwise Disclose such information shall also be deemed Confidential Information. Information originally designated as Confidential Information shall not retain that status after any ruling by the Court denying such status to it. No information that is in the public domain, or that the producing

Person possesses on a non-confidential basis, shall be deemed "Confidential Information" under this Order.

(d) "**Disclose**" means show, divulge, reveal, produce, describe, transmit, or otherwise communicate, in whole or in part.

(e) "**Document**" means documents or electronically stored information as defined in Fed. R. Civ. P. 34(a).

(f) "**Non-Pharmaceutical Expert**" means all experts and consultants who are not Pharmaceutical Experts or Consultants, as defined in Paragraph 1(h), and who do not regularly consult or advise pharmaceutical companies on commercial matters, research and development, or regulatory issues, including but not limited to trial consultants, graphic or audiovisual consultants, or economic experts.

(g) "**Parties**" means collectively the Plaintiffs and Defendants to this Action.

(h) "**Person**" means any natural person, corporate entity, partnership, association, joint venture, governmental entity, or trust.

(i) "**Pharmaceutical Expert or Consultant**" means any independent consultant or expert who has expertise in the research, development, marketing, or approval of pharmaceuticals, assists or consults with, or within the past three years has assisted or consulted with, pharmaceutical companies regarding marketing of development of, or obtaining of approval of, pharmaceutical products—but which specifically does not include any trial consultants, graphic or audiovisual consultants, or economic experts.

(j) "**Pharmaceutical Expert Notice**" means notice given to opposing counsel of the identity and current resume or curriculum vitae of a Pharmaceutical Expert or Consultant.

(k) "**Protected Information**" means, collectively, information designated as "Confidential" and/or information designated as "Confidential – Attorneys' Eyes Only."

(l) "**Protected Person**" means any person (including a Party or non-party) who produces any Documents, testimony or other material or information in this Action.

B. DESIGNATION OF CONFIDENTIAL INFORMATION AND ATTORNEYS' EYES ONLY INFORMATION

2. A Protected Person may designate as "Confidential Information" any information that it provides to a Party or otherwise Discloses pursuant to this Action, to the extent such information constitutes Confidential Information as defined in Paragraph 1(b) of this Order. Such designations constitute a representation to the Court that such Protected Person believes, in good faith, that the information so designated constitutes Confidential Information.

3. A Protected Person may designate as "Attorneys' Eyes Only Information" any Confidential Information that Person in good faith believes to reveal or reflect: (i) highly sensitive trade secrets, intellectual property, or proprietary technical information, including, without limitation, research information, design and technical Documents and internal product specifications; (ii) highly sensitive business, financial or marketing information, including, without limitation, licenses, forecasts, customer lists, pricing data, cost data, customer orders, customer quotations and marketing plans; (iii) pending or abandoned patent, trademark and copyright applications, foreign or domestic, unless published or otherwise publicly available; or (iv) such other Documents, information, or materials that relate to proprietary information that the Person believes is entitled to extraordinary protection or is of such nature and character that the unauthorized disclosure of such information is likely to harm the competitive or economic position of the Person or provide improper advantage to others. Such designations constitute a

representation to the Court that such Protected Person believes, in good faith, that the information so designated constitutes Attorneys' Eyes Only Information.

4. Any Disclosure of information not designated as Confidential Information or Attorneys' Eyes Only Information will not be deemed a waiver of any future claim of confidentiality concerning such information if it is later designated Confidential Information or Attorneys' Eyes Only Information pursuant to Paragraph 6 of this Order. However, any such subsequent designation will not retroactively prohibit the Disclosure of any information for which Disclosure was proper when made.

5. Designation as Confidential Information or Attorneys' Eyes Only Information of deposition transcripts and Documents produced during this Action is governed as follows:

(a) Whenever discovery is sought by subpoena from a non-party in this Action after entry of this Order, a copy of this Order shall accompany the subpoena.

(b) A Protected Person that designates as Confidential Information or Attorneys' Eyes Only Information any material produced in this Action after entry of this Order must stamp or label the material with the designation "**CONFIDENTIAL**" or if applicable "**ATTORNEYS' EYES ONLY**." If a Party initially produces Documents for inspection (e.g. because of the volume of materials and to reduce unnecessary copying), in lieu of marking the original of a Document which contains Confidential Information prior to such inspection, counsel for the producing Party may in writing designate Documents or things being produced for inspection as containing Confidential Information, thereby making them subject to this Order; however, any copies of Documents thereafter provided must be marked by the producing Protected Person in accordance with this Order at the time copies are formally produced. If material cannot be labeled, it may be designated Confidential Information pursuant to this Order

by placing the legend "**CONFIDENTIAL**" or if applicable "**ATTORNEYS' EYES ONLY**" on the label of the disk containing such Documents. Tangible objects constituting or containing Confidential Information may be designated Confidential Information by affixing to the object or its container, a label or tag marked "**CONFIDENTIAL – SUBJECT TO CONFIDENTIALITY ORDER**," or if applicable **"CONFIDENTIAL - ATTORNEYS' EYES ONLY – SUBJECT TO CONFIDENTIALITY ORDER."**

(c) All deposition testimony shall be treated as containing Protected Information and subject to this Order until a time thirty (30) calendar days following receipt of the final transcript by counsel for the disclosing Party. In the event that the disclosing Party or any other Party wishes testimony or information Disclosed at a deposition to be treated as Protected Information thereafter, that Party shall designate such testimony or information as Protected Information by either notifying the other Party in writing, within thirty (30) calendar days following receipt of the final transcript, or designating during the deposition the transcript or portions thereof as Protected Information, and by specifying whether then information is to be treated as Confidential Information or as Confidential - Attorneys' Eyes Only information. Documents and things already designated as Protected Information which are used as exhibits shall remain as such. If during a Court proceeding Protected Information is likely to be revealed, any Party may request that the proceeding be held in camera. If such request is granted by the Court, the transcript of such proceedings shall be treated as a deposition transcript for the purposes of this Order. Nothing in this Order precludes a Party from opposing any request that a proceeding be held in camera or otherwise be closed to the public. Any Party may designate the deposition testimony of any third Party as confidential and the provisions of this Paragraph may be invoked.

6. In the event that a Party seeks discovery from a non-party to this suit, the non-party will be provided with a copy of this Order and may invoke its terms with respect to any Protected Information provided to the Parties. If any Protected Information is produced by a Person other than a Party pursuant to this Order, such Person shall be considered a "designating Party" within the meaning of that term as it is used in the context of this Order, and both Parties to this Order should be treated as receiving Parties. The Parties recognize that, during the course of this litigation, Protected Information that originated with a Person other than a Party and for which there exists an obligation of confidentiality may be produced. Such information that the designating Party believes originated with such Person, but is subject to a confidentiality obligation, may be designated as Protected Information and the provisions of this Order shall apply to such discovery as if such discovery were being provided by a Party. Nothing in this Order prohibits a Party from negotiating a separate order with a third Party.

7. Nothing in this Order shall be deemed to enlarge or diminish any Person's rights and/or obligations with respect to Protected Information rightfully received at any time under no obligation or different obligation of confidentiality. Nothing contained herein shall be construed to restrict disclosure and use of Documents, information, or things obtained through discovery, whether or not deemed confidential hereunder, to any Person who had previously prepared, lawfully received, or had rightful access to such Documents, information, or things. Nothing contained herein shall be construed to restrict disclosure and use by the receiving Party of any Protected Information of another Party should such Documents, information, or things become publicly available through no fault or wrongdoing of the receiving Party.

8. In the event a Party or Person producing information, through inadvertence, produces or provides information without correctly designating it Protected Information as

provided in this Order, the producing Party may give written notice to the receiving Party or Parties that the Document, thing, other discovery information, response or testimony is Protected Information and shall be treated in accordance with the provisions of this Order. The receiving Party or Parties must treat such Documents, things, information, responses and testimony as Protected Information from the date such notice is received in accordance with the provisions of this Order. Upon receipt of such notice, the receiving Party shall return or destroy said unmarked or incorrectly marked Documents, things, information, responses and testimony and all notes and other Documents referring to that material shall only be retained by outside attorneys identified in paragraph 10(a) below. Upon notice to the receiving Party of such failure to designate, the receiving Party shall reasonably cooperate to correct any disclosure to maintain the confidentiality of the inadvertently Disclosed information, without prejudice. Within five (5) business days of providing written notice that a Document or Documents was inadvertently not designated Protected Information under this provision, the producing Party must provide the receiving Party with replacement copies of such Documents containing the proper designation.

9. Nothing herein shall prevent a receiving Party from contending (for the purposes of securing an order so providing from the Court) that any or all Protected Information is not confidential or otherwise not entitled to protection. Any receiving Party may at any time request that the designating Party cancel or change the Protected Information designation with respect to any Document, object or information. Such request shall be written, shall be served on counsel for the designating Party and shall particularly identify the designated Protected Information that the receiving Party contends is not entitled to either Confidential or Confidential - Attorneys' Eyes Only protection and the reasons supporting its contention. If a dispute as to a Confidential or Attorneys' Eyes Only designation of a Document cannot be resolved by agreement, the

proponent of the designation being challenged shall present the dispute to the Court initially by telephone or letter, in accordance with Local Civil Rule 37.1(a)(1), before filing a formal motion for an order regarding the challenged designation. The document or information that is the subject of the filing shall be treated as originally designated pending resolution of the dispute

C. SCOPE OF DISCLOSURE OF CONFIDENTIAL AND ATTORNEYS' EYES ONLY INFORMATION

10. Except as authorized by this Order, information designated as Confidential Information pursuant to this Order shall not be Disclosed to any Person other than as set forth below, and may be Disclosed to and used by the Persons set forth below only in this Action:

(a) Outside attorneys of record for any Party and stenographic, clerical and paralegal employees or independent contractors (e.g., photocopiers, electronic discovery vendors, translators, interpreters, etc.) of such attorneys as well as other members, partners, shareholders, associate attorneys, and other employees of such attorneys' law firms. At present, such firms are: Wilson Sonsini Goodrich & Rosati PC, Saiber LLC, Jones Day, and Norris McLaughlin & Marcus, P.A., but this provision shall include any other law firms whose attorneys enter an appearance and sign this Order. Outside attorneys are those not employed by a Party or related entity and include attorneys employed by firms of record even if not otherwise identified specifically on pleadings.

(b) Independent consultants or experts (and their staff) retained by the attorneys for the Parties either as technical consultants or expert witnesses for the purposes of this litigation, as long as these Personnel comply with the procedure of Paragraphs 14 and 15 herein;

(c) Each Person or firm retained by Plaintiff or Defendant for the purpose of producing graphic or visual aids or providing any other litigation support services, as long as these personnel comply with the procedure of Paragraph 15 herein;

(d) The Court and all Persons assisting the Court in this Action, including judges and their staff, law clerks, court reporters, and stenographic, videographic or clerical Personnel;

(e) Three attorneys employed by Plaintiff and three attorneys employed by Defendant ("inside counsel"), provided that before such attorneys receive any disclosure as permitted under this Order of Confidential Information, each attorney shall review and agree to be bound by the terms of this Order by signing the Declaration of Compliance. Production sets of Documents containing Confidential Information shall be maintained at the offices of outside attorneys of record only. To the extent Confidential Information is provided to inside counsel at their offices, that information shall be maintained in a secure fashion and shall not be shared or disseminated. Inside counsel may retain only one copy of any Document produced by the opposing Party and shall make no additional copies of the information or Documents received. An in-house attorney can be substituted at any time upon agreement of the Parties or for good cause shown upon order of the Court. Subject to the foregoing, the Parties designate the following in-house attorneys:

A. For Mylan: Jill Ondos, Douglas Miner and Brian Cuthbertson

B. For Celgene:

The foregoing lists in this Paragraph may be expanded by mutual agreement in writing by counsel for Plaintiffs and Defendants.

(f) Any other Person agreed to by the Parties or permitted by the Court, as long as such Persons comply with the procedure of Paragraphs 14 and 15, if applicable, herein.

11. Except as provided elsewhere in this Order, information designated as Confidential - Attorneys' Eyes Only information may be Disclosed only to the following individuals:

(a) Outside attorneys of record for any Party and stenographic, clerical and paralegal employees or independent contractors (e.g., photocopiers, electronic discovery vendors, translators, interpreters, etc.) of such attorneys as well as other members, partners, shareholders, associate attorneys, and other employees of such attorneys' law firms. At present, such firms are: Wilson Sonsini Goodrich & Rosati PC, Saiber LLC, Jones Day, and Norris McLaughlin & Marcus, P.A., but this provision shall include any other law firms whose attorneys enter an appearance and sign this Order. Outside attorneys are those not employed by a Party or related entity and include attorneys employed by firms of record even if not otherwise identified specifically on pleadings.

(b) Independent consultants or experts (and their staff) retained by the attorneys for the Parties either as technical consultants or expert witnesses for the purposes of this litigation, as long as these Personnel comply with the procedure of Paragraphs 14 and 15 herein;

(c) Each Person or firm retained by Plaintiffs or Defendants for the purpose of producing graphic or visual aids or providing any other litigation support services, as long as these personnel comply with the procedure of Paragraph 14 herein; and

(d) The Court and all Persons assisting the Court in this Action, including judges and their staff, law clerks, court reporters, and stenographic, videographic or clerical personnel;

(e) Any other Person agreed to by the Parties or permitted by the Court, as long as such Persons comply with the procedure of Paragraphs 14 and 15, if applicable, herein.

12. Before any information designated as Confidential Information or Attorneys' Eyes Only Information may be Disclosed to any Person specified in Paragraphs 10 (b), 10 (c), 10 (e), 10 (f) or 11 (b), 11 (c), 11 (e) of this Order, he or she must first read this Order or must have otherwise been instructed on his or her obligations under the Order by this Court or counsel for a Party, and shall have executed the agreement included as Appendix A hereto. Counsel for the Party making the disclosure must retain the original of such executed agreement for a period of at least one year following the final resolution of this Action. Copies of Declarations signed by Pharmaceutical Experts or Consultants shall be provided promptly to opposing counsel. Copies of Declarations signed by Non-Pharmaceutical Experts or Consultants or Persons designated in accordance with Paragraph 10(e) shall not be provided to opposing counsel.

13. Each individual described in Paragraph 10 of this Order to whom information designated as Confidential Information is Disclosed, and each individual described in Paragraph 11 to whom information designated Attorneys' Eyes Only Information is Disclosed, must not Disclose that Confidential Information or Attorneys' Eyes Only Information to any Person except as provided in this Order.

14. Nothing in this Order:

(a) limits a Person's use or Disclosure of its own information designated as Confidential Information or Attorneys' Eyes Only Information;

(b) prevents Disclosure of Confidential Information or Attorneys' Eyes Only Information by any Party to any current employee of the Person that designated the information as Confidential Information or Attorneys' Eyes Only Information; or

(c) prevents Disclosure of Confidential Information or Attorneys' Eyes Only Information by any Party with the consent of the Person that designated the information as Confidential Information or Attorneys' Eyes Only Information;

D. USE OF PROTECTED INFORMATION BY EXPERTS AND CONSULTANTS

15. Before any Pharmaceutical Expert or Consultant is afforded access to another Party's Protected Information, the identity and current resume or curriculum vitae of the Pharmaceutical Expert or Consultant shall be furnished to all Parties, along with a copy of the agreement included as Appendix A hereto signed by the Pharmaceutical Expert or Consultant. These materials may be provided at any time after this Order is signed by the Parties. No Protected Information shall be Disclosed to such Pharmaceutical Expert or Consultant until after the expiration of a ten (10) business day period commencing upon the receipt by opposing counsel of a Pharmaceutical Expert Notice. If, within ten (10) business days of receipt of a Pharmaceutical Expert Notice, any Party objects, in writing and with an explanation of the basis for the objection, to the proposed disclosure to the expert, the Parties shall then have three (3) additional business days after an objection is raised to use good faith efforts to reach an agreement regarding the proposed disclosure to the expert, during which period of time disclosure may not be made absent an agreement. If agreement cannot be reached, the Party objecting to disclosure may apply to the Court for relief within five (5) business days after it is determined that an agreement cannot be reached. The burden shall be on the objecting Party to show the Court good cause why the disclosure should not be made. In the event an application is

made to the Court, however, the materials will continue to be treated as Protected Information in accordance with this Order during the time the Court considers the application and will not be Disclosed to the Pharmaceutical Expert or Consultant.

16. For all Non-Pharmaceutical Experts, the independent consultant or expert shall be provided with a copy of this Order and shall execute a copy of the agreement included as Appendix A hereto confirming the Non-Pharmaceutical Expert's agreement to be bound by the terms of this Order. Counsel shall retain the original Declaration of Compliance by the Non-Pharmaceutical Expert, but no further steps are required before access to Protected Information is afforded to a Non- Pharmaceutical Expert.

E. STIPULATION

17. A deposition notice will be sufficient to require any testifying expert to appear for a deposition and to produce discoverable material in his/her possession, custody, or control. Absent good cause, no subpoena shall be served on a witness individually based on his/her role as a testifying expert. Within seven (7) days of service of any expert report any data, Documents, or other information on which the expert relied in forming his/her opinion. Examination at deposition or trial will be permitted as to any information on which the expert has or will rely in forming his/her opinion.

18. Drafts of expert reports or declarations and notes, written communications, and other types of preliminary work created or generated by or for experts or their staff (unless such notes are generated while testifying) are exempt from discovery. Communications between and among (a) experts, including their staff, and outside counsel, (b) experts, including their staff, and other experts or consultants and their respective staff, and/or (c) experts and their respective

staff shall not be discoverable unless that the expert specifically relied upon any such communications as a basis for any of his or her ultimate opinions or reports.

19. Suggestions from outside counsel regarding revisions to the form of the expert's report or additional support for the expert's ultimate opinions are examples of communications that are protected from discovery under this Order.

20. Nothing in this Stipulation shall be construed to preclude (a) the use of non-protected materials by any Party; or (b) a Party from seeking to challenge a designation of any material(s) as Protected Information under this Order.

F. DISCLOSURE OF CONFIDENTIAL AND ATTORNEYS' EYES ONLY INFORMATION IN THIS ACTION

21. If any information designated under this Order as Confidential Information or Attorneys' Eyes Only Information is included in any pleading, motion, exhibit, or other paper to be filed with the Court, the Party or other Person seeking to file such material shall contemporaneously file a Motion to Seal such papers in accordance with the procedures set forth in New Jersey Civil Rule 5.3(c) seeking to shield such material from public disclosure and shall follow the procedures specified by Rule 5.3(c)(1)-(5). Pursuant to New Jersey Civil Rule 5.3(c)(2), if the information required in support of the Motion to Seal is not within the knowledge of the movant, supplemental motion papers in support of the motion may be filed by a Party or Person having such knowledge no later than fourteen days after the filing of the motion. Nothing in this provision prohibits a Party from challenging a designation of information as Confidential Information or Attorneys' Eyes Only Information pursuant to Paragraph 9 of this Order, and nothing in this Order shall restrict any Person, including any

member of the public, from challenging the filing of any Confidential Information or Attorneys' Eyes Only material under seal.

22. Submissions filed under seal shall not be available for inspection except by the Court and authorized Persons as set forth in Paragraphs 10 and 11 of this Order. Nothing in this Order shall prohibit the right of one Party to request from another Party claiming confidentiality that the designated Pleading and Discovery Materials be released from the confidentiality restriction for all purposes or for limited purposes (such as to show certain designated Persons). Any such requests and resulting permission shall be in writing and shall be considered by the receiving Party in a reasonable manner.

23. The use of Confidential Information and Attorneys' Eyes Only Information at judicial proceedings shall be governed by New Jersey Civil Rule 5.3(c). Where the Court requires designation of exhibits and deposition testimony in advance of a hearing, the Party shall file a Motion to Restrict Access in accordance with the procedures set forth in New Jersey Civil Rule 5.3(c) seeking to restrict public access to the Confidential Information and Attorneys' Eyes Only Information in the designated exhibits and/or deposition testimony, and shall follow the procedures specified by Rule 5.3(c)(1)-(5), provided, however, that pursuant to New Jersey Civil Rule 5.3(c)(2), if the information required in support of the Motion to Restrict Access is not within the knowledge of the movant, supplemental motion papers in support of the motion may be filed by a Party or Person having such knowledge no later than fourteen days after the filing of the motion or within a shorter period if set by the Court, and further provided that the burden of restricting public access to Confidential Information and Attorneys' Eyes Only Information in a judicial proceeding shall at all times remain with the Person that designated the information as Confidential Information or Attorneys' Eyes Only Information.

24. All materials produced or exchanged in connection with this Action, including but not limited to Confidential Information and Attorneys' Eyes Only Information, produced by a Party or non-party as part of this proceeding shall be used solely for purposes of the conduct of this Action and shall not be used for any business, commercial, competitive, Personal, or other purpose. It shall be the duty of each Party and each individual having notice of this Order to comply with this Order from the time of such notice. At any time a Party may move the Court to modify this or any other provision of this Order upon good cause shown.

25. In the event that a Party seeks to question a witness at a deposition, hearing, or trial about Protected Information that the witness is not otherwise authorized to access under this Order, the Party who wishes to Disclose the Protected Information must first seek permission to do so from the Party who designated the material as being Protected Information. If permission is denied, the Party seeking to Disclose the Protected Information may present an application to the court for leave to Disclose such information to the witness as at issue. In making such an application, the burden shall be on the requesting Party to demonstrate good cause for making the disclosure.

26. Nothing contained in this Order shall be construed to limit any Party's rights (a) to use, in taking depositions of a Party, its employees, former employees or its experts or in briefs or at trial or in any proceeding in this litigation, any Protected Information of that Party, or (b) to Disclose Protected Information to any witness at a deposition or at trial who either wrote (in whole or in part), received, or lawfully has or had rightful access to such information. In addition, a witness may be shown any Document that contains or reveals Protected Information if the witness (a) is a 30(b)(6) witness testifying on behalf of the producing Party, (b) is a present officer, director or employee of the producing Party, (c) was an officer or director of the

producing Party at the time the Document was sent and/or created, (d) was an employee of the producing Party at the time the Document was sent and/or created and is not then-employed by a competitor of the producing Party, or (e) was an employee of the producing Party at the time the Document was sent and/or created whose duties or position while with the producing Party would have provided access to the type of Protected Information at issue.

27. Nothing in this Order shall prevent a Party from attempting to examine as witnesses, during depositions or at trial, Persons not authorized to receive Documents designated as Protected Information, as identified herein, if the examination concerns a Document that the witness previously had actual lawful access to or prior knowledge of as demonstrated by the Document itself or by foundation testimony. Nor shall this Order prevent counsel from examining a witness to determine whether he or she has prior knowledge of Protected Information, so long as such examination shall be in a manner that does not Disclose the details of the designated Documents. Any Protected Information so used shall not lose its confidential status through such use and its confidentiality shall be protected in conformance with this Order.

G. INADVERTENT PRODUCTION OF PRIVILEGED MATERIAL

28. The inadvertent production of Documents that are subject to the attorney-client privilege, the attorney work-product doctrine, or any other applicable privilege or protection from disclosure will not waive the privilege or protection from disclosure. In addition, if Documents subject to the attorney-client privilege, the attorney work-product doctrine, or any other applicable privilege or protection from disclosure are included in Documents made available for inspection, such disclosure shall not be considered a waiver of the privilege or protection from disclosure. The Party or Protected Person that produced the material must notify the receiving Person promptly after becoming aware of the inadvertent disclosure of privileged

or protected information, and the receiving Person's treatment of such material shall be in accordance with the Federal Rule of Civil Procedure 26(b)(5)(B).

29. Upon receiving notice from a Party or Protected Person that it has inadvertently produced privileged or otherwise protected Documents, the Party that received said Documents shall not review, copy or disseminate such Documents or information. The Party that received said Documents shall immediately return all copies to the Party or Protected Person that produced the material or certify that all copies have been destroyed. In all events, such return must occur within three (3) business days of receipt of notice or discovery of the inadvertent production. The Party to whom production was made will further certify that it has destroyed all notes, excerpts, summaries, or any other materials containing information from said Documents.

30. In the event the receiving Party contends the Documents or information is not privileged, the receiving Party shall promptly notify the producing Party that it intends to move for an order allowing the use of an inadvertently produced privileged Document in the litigation. Once the receiving Party notifies the producing Party that it intends to move for an order that the Document in question is not properly subject to any privilege claim, it must file its motion within fourteen (14) days of providing such notice. The motion shall be filed under seal as described in Paragraph 21 of this Order. In connection with such a motion, the challenging Party shall not assert as a ground for production the fact or circumstances of the inadvertent production. The Party asserting the privilege shall file its opposition under seal and submit a copy of the Document in question for in camera review by the court.

H. PROCEDURES UPON TERMINATION OF THIS ACTION

31. The provisions of this Order shall survive the termination of this Action. Within sixty (60) days after the case is terminated (including all appeals), such Party shall return to the

designating Party or shall destroy, at the option of counsel in possession of such copies, all Documents, objects and other materials produced as or designated as Protected Information, including extracts or summaries thereof, and all reproductions thereof, including but not limited to that given to experts and inside counsel. If the materials are destroyed, counsel responsible for the destruction shall within ten (10) calendar days of such destruction certify to counsel for the designating Party that destruction has taken place. Notwithstanding the foregoing, outside counsel for each Party may retain (a) one copy or sample of all material designated Protected Information for reference in the event of disputes over the use or disclosure of such material, (b) Documents, things, copies and samples to the extent they include or reflect receiving attorney's work product, and (c) pleadings or other papers filed with the Court or served in the course of the litigation, the depositions, the deposition exhibits and the trial record.

I. RIGHT TO SEEK MODIFICATION

32. This Order may be amended with respect to (a) specific Documents or items of Protected Information or (b) Persons to whom Protected Information may be Disclosed, by Court order or by written agreement of the Parties hereto. This Order shall remain in force and effect indefinitely until modified, superseded or terminated by order of this Court.

33. Nothing in this Order prevents any Person, including members of the public, from seeking modification of this Order, upon motion made pursuant to the rules of this Court.

J. MISCELLANEOUS

34. This Order is intended to provide a mechanism for handling the disclosure or production of Protected Information to which there is no objection other than confidentiality. Neither the agreement of the Parties with respect to Protected Information, nor the designation of

any information, Document or the like as Protected Information, nor the failure to make such designation shall constitute evidence with respect to any issue on the merits in this action..

35. This Order is without prejudice to the right of any Party to seek further or additional protection of information for which the protection of this Order is not believed by such Party to be adequate. Nothing in this Order shall be deemed to bar or preclude any Party from seeking such additional protection, including, without limitation, an order that certain matters may not be discovered at all.

36. Prompt written notice (here, meaning no more than the two business days) shall be given to any Party who produced Protected Information hereunder, in the event that said Party's Protected Information is sought by any Person not a Party to this litigation, by subpoena in another action or by service with any legal process. Any Person seeking such Protected Information who takes action to enforce such subpoena or other legal process shall be apprised of this Order. The Party receiving a subpoena or other legal process shall not produce any Protected Information until any dispute regarding production is resolved and, in any event, no earlier than five (5) days after providing notice to the producing Party of the receipt of the subpoena or other legal process. Nothing herein shall require anyone covered by this Order to contest a subpoena or other legal process, or to appeal any order requiring production of Protected Information, or to subject itself to penalties for non-compliance with any legal process or order, provided the Party has notified the producing Party that Protected Information has been subpoenaed or otherwise requested.

37. The entry of this Order shall not be construed as a waiver of any right to object to the furnishing of information in response to discovery and, except as expressly provided herein, shall not relieve any Party of the obligation of producing information in the course of discovery.

38. Nothing in this Order shall bar or otherwise restrict counsel from rendering advice to his or her client with respect to this action and, in the course thereof, relying in a general way upon his or her examination of Protected Information produced or exchanged in this action; provided, however, that in rendering such advice and in otherwise communicating with a Person not entitled to view any Protected Information, the attorney shall not Disclose the contents of Protected Information produced by any other Party or non-party.

39. All notices required by any paragraphs of this Order are to be made by email to counsel representing the noticed Party. The date by which a Party receiving notice shall respond or otherwise take action shall be computed from the date of receipt of the notice. For any notice required under this Order, notice received after the close of business (6:00 p.m. Eastern time) shall be deemed received on the following working day. Any of the notice requirements herein may be waived in whole or in part, but only in a writing signed by an attorney for the Party from whom waiver is sought. Unless otherwise noted, all specified time periods are in calendar days.

40. Each individual who receives information designated as Confidential Information or Attorneys' Eyes Only Information under this Order agrees to subject himself/herself to the jurisdiction of this Court for the purpose of any proceedings relating to the performance under, compliance with, or violation of this Order.

We hereby consent to the form and entry of this Stipulated Discovery Confidentiality Order.

Arnold B. Calmann (abc@saiber.com)
Jakob B. Halpern (jbh@saiber.com)
SAIBER LLC
One Gateway Center
Newark, New Jersey 07102-5311
Telephone: (973) 622-3333
Facsimile: (973) 622-3349

Of counsel:

Seth C. Silber (ssilber@wsgr.com)
Jonathan R. Lutinski (jlutinski@wsgr.com)
Valentina V. Rucker (vrucker@wsgr.com)
Roisin Comerford (rcomerford@wsgr.com)
WILSON SONSINI GOODRICH & ROSATI
1700 K St N.W., 5th Floor
Washington, DC 20006

Attorneys for Plaintiff Mylan Pharmaceuticals Inc.

Norris McLaughlin & Marcus, P.A.
721 Route 202/206, Suite 200
P.O. Box 5933
Bridgewater, New Jersey 08807

Of counsel:

[JONES DAY]

Attorneys for Defendant Celgene

Dated: June __, 2012

For good cause shown, it is so ordered.

Dated this _____ day of _____, 2014.

HONORABLE Michael A. Hammer, U.S.M.J.

Appendix a

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MYLAN PHARMACEUTICALS INC., Plaintiff, vs. CELGENE CORPORATION, Defendant.	)	Civil Action No. 14-2094-ES-MAH

UNDERTAKING TO ABIDE BY STIPULATED DISCOVERY CONFIDENTIALITY ORDER

I, _____, declare that my address is _____.

My current employer is _____.

My current occupation is _____.

I hereby certify that:

1. I have received a copy of the Stipulated Discovery Confidentiality Order in the above-captioned action. I have carefully read and understand the provisions of the Discovery Confidentiality Order.

2. I agree to be bound by the terms of the Stipulated Discovery Confidentiality Order and agree to use information, designated as Confidential Information or Attorneys' Eyes Only Information, provided to me only for the purpose of this litigation.

3. I understand that my failure to abide by the terms of the Stipulated Discovery Confidentiality Order entered in the above-captioned action will subject me, without limitation, to civil and criminal penalties for contempt of Court.

4. I hereby submit to the jurisdiction of this Court (the United States District Court for the District of New Jersey) for the purpose of enforcement of the Stipulated Discovery Confidentiality Order in this action.

5. I make this certificate this ____ day of _____, 201__.

Signed: _____

EXHIBIT B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MYLAN PHARMACEUTICALS INC. Plaintiff, vs. CELGENE CORPORATION, Defendant.	No. Civil Action No.: 14-2094-ES-MAH **STIPULATED ELECTRONICALLY STORED INFORMATION PROTOCOL** *DOCUMENT FILED ELECTRONICALLY*

ELECTRONICALLY STORED INFORMATION PROTOCOL

I. DEFINITIONS

A. "**Electronically stored information**" or "**ESI**," as used herein, means and refers to computer generated information or data of any kind, stored in or on any storage media located on computers, file servers, disks, tape or other real or virtualized devices or media. The parties agree to treat ESI as set forth in this Protocol without waiving the right to object to the production of a specific type of ESI in this case, including but not limited to objections for relevance, undue burden, and/or inaccessibility.

B. "**Documents**" shall have the same definition as set forth in Federal Rule of Civil Procedure 34.

C. "**Native data format**" means and refers to the format of ESI in which such ESI was generated or used by the producing party in the usual course of business and in its regularly conducted activities.

D. "**Metadata**" means (i) information associated with a native file that is not ordinarily viewable or printable from the application that generated, edited, or modified such native file which describes the characteristics, origins, usage or validity of the electronic file or (ii) information generated automatically by the operation of a computer or other information technology system when a native file is created, modified, transmitted, deleted or otherwise manipulated by a user of such system.

E. "**Static Image**" means or refers to a representation of ESI produced by converting a native file into a standard image format capable of being viewed and printed on standard computer systems. A Tagged Image File Format (TIFF) image is an example of a Static Image.

F. "**Load/Unitization file**" means an electronic file containing information identifying a set of paper-scanned images or processed ESI and indicating where individual pages or files belong together as documents, including attachments, and where each document begins and ends. A Load/Unitization file will also contain data relevant to the individual Documents, including extracted and user created Metadata, as well as OCR or Extracted Text, should such data be available.

G. "**OCR File**" means the optical character recognition file which is created by software used in conjunction with a scanner that is capable of reading text-based documents and making such documents searchable using appropriate software.

H. "**Extracted Text**" means the text extracted from a Document, and includes all header, footer and document body information when available.

I. "**Media**" means an object or device, including but not limited to a disc, tape, computer or other device, on which data is or was stored.

J. "**Parties**" means or refers to the named plaintiffs and defendants in the above captioned matter, as well as any later added plaintiffs and defendants.

II. SEARCH PROTOCOL FOR ELECTRONIC DOCUMENTS

A search protocol for electronic documents is still pending agreement by the parties. The parties will submit a joint proposal or separate proposals regarding this issue on or before [DATE].

III. FORMAT OF PRODUCTION

A. Document Image Format. With the exception of (i) databases discussed in Section III.J, (ii) ESI discussed in Section III.B, and (iii) prior production sets discussed in Section III.K below or unless otherwise agreed to in writing by a requesting party, at the sole option and cost of the producing party, non-reimbursable and non-taxable pursuant to 28 U.S.C.§ 1920 or any other cost-recovery provision, ESI must be produced electronically as a single-page Black & White GROUP IV "TIFF" image where the original document was in black and white or a Color Medium Quality JPEG where the original document was in color and where the color contributes to meaning, context, or content of the document. In addition, the producing party will honor reasonable requests made in good faith for either the production of the original document for inspection and copying or production of a color image of the document. In all cases the image must reflect how the source document would have appeared if printed out to a printer attached to a computer viewing the file. Provided, however, that, if a producing party has (a) reasonably notified a requesting party in writing that it objects on grounds of undue burden to production of certain documents, (b) reasonably identified the basis and scope of its claim of undue burden, and (c) reasonably identified the need to convert such documents to "TIFF" format and the costs that such conversion would entail as aspects of the undue burden asserted, then the producing party will not be precluded from seeking an agreement or court order that such costs should in whole or in part be shifted to, reimbursed by, or taxed against the requesting party; and further provided that no party shall be precluded from seeking recovery or taxation of costs for conversion to "TIFF" format of documents that the party can establish could not reasonably be produced as an initial matter in their native file formats.

Nothing in this Section or the remainder of this protocol precludes the requesting party from opposing any applications for shifting of costs.

1. When processing ESI for review and for production in TIFF format, the producing party will instruct its vendor to force off Auto Date and force on hidden columns or rows, hidden worksheets, speaker notes, track changes, and comments.

2. When processing ESI, GMT or EST should be selected as the time zone and the producing party will note the time zone used in its processing. To the extent that a party has already processed ESI using a different time zone, the producing party will note the time zone used in its processing. Otherwise, Parties shall consistently produce all ESI processed using the same time zone. When a metadata field includes a date, the date shall be provided in the format defined in Section III.H below.

3. The parties shall meet and confer to the extent reasonably necessary to facilitate the import and use of the produced materials with commercially available document management or litigation support software.

B. Native File Format. Spreadsheets, power point presentations, audio files and video files will be produced in native format. A duplicate of the first page of such documents or a slip sheet placeholder must be produced in TIFF format to facilitate database referencing and Bates and confidentiality stamping. Such duplicate first page or slip sheet placeholder will be endorsed as defined in Section III.F below. The associated Load/Unitization file shall include a link to the native item.

If production in native format is necessary to decipher the meaning, context, or content of a document produced in TIFF, the producing party will honor reasonable requests made in good faith for either the production of the original document for inspection and copying or production of the document in native format within ten (10) business days. Documents that are to be produced in a native format, but that require redactions will be produced as TIFF images with the relevant portions

redacted, or if a TIFF image production is not practicable (e.g., the file is a video or very large spreadsheet), as a copy of the native file with the relevant portions replaced with "[REDACTED]" or a similar mark. If modification of a native file is required for redaction purposes, metadata information associated with that file should remain unchanged unless it also requires redaction.

C. Production of Physical Documents. Documents or records which either were originally generated as or converted into ESI but now only exist in physical hard-copy format, or documents or records that were originally generated in hard-copy format, shall be converted to single page image files (BLACK AND WHITE Group IV Tiff or Medium Quality Color JPEG) and produced following the same protocols set forth herein or otherwise agreed to by the parties. All such documents will be produced with an OCR file as outlined in Section III.D below.

D. Document Unitization. For files produced as either BLACK AND WHITE Group IV TIFF or Medium Quality Color JPEG images, each page of a document shall be electronically saved as an image file. If a document consists of more than one page, the unitization of the document and any attachments and/or affixed notes shall be maintained as it existed in the original when creating the image files.

The producing party shall produce a Load/Unitization file for all produced documents in accordance with the following formatting:

OCR and Extracted Text Files (.TXT Files):

ESI shall be produced with multi-page searchable Extracted Text. For ESI from which text cannot be extracted, OCR will be produced instead. Any such Extracted Text or OCR will be produced on a document level in the following format:

- Produce a single text file per document containing all the document's pages
- Pages separated by form feed character (decimal 12, hex 0xC)
- Filenames must be matched bates number in this form:

  <Bates num>.txt

Where <Bates num> is the BATES number of the first page in the document.

- Text must be encoded in UTF-8.
- Text files will be located in a directory named "TEXT" that is separate from the TIFF image.

Images Files:

- Single page per image
- Black and White Group IV TIFF and Medium Quality Color JPEG are the default FORMATS
- Filenames for images must be matched bates number in this form:

  <Bates num>.<ext>

  Where <Bates num> is the BATES number of the page, and <ext> is the appropriate extension for the image format (.jpg, .tif).

Load/Unitization Files:

- "Concordance Default" delimited text file utilizing the following characters:
  - The "comma" delimiter is "" (020)
  - The "quote" delimiter is "þ" (254)
  - The "new line" delimiter is "®" (174)
- First line must contain the column/field names (set forth in Paragraph 1(c) herein)
- Every row must have the same number of columns/fields (empty values are acceptable)
- Text must be encoded in UTF-8
- LFP IPRO LOAD FILE with relative pathing to the image files
- OPT OPTICON LOAD FILE with relative pathing to the images file.

Notwithstanding the foregoing, the parties agree to further meet and confer, as necessary, in advance of any production of documents, and in consultation with their respective vendors, to confirm all Load/Unitization file specifications.

E. DEDUPLICATION. To the extent that exact duplicate documents (based on MD5 or SHA-1 hash values) reside within a party's ESI data set, each party may produce only a single copy of a responsive document or record ("Single Production Copy"). Exact duplicate shall mean bit-for-bit identicality of the document content. For exact duplicate documents, the producing party will produce the metadata described in Section III.H herein for the Single Production Copy, as well as any such metadata that differs for the duplicate document(s). Where an exact duplicate document has attachments, hash values must be identical for both the document-plus-attachment (including associated metadata) as well as for any attachment (including associated metadata) standing alone. If not, any such family must be produced without deduplication of any family member. Similarly, the same criteria shall be applied to duplicate documents that are attachments to a parent document. In the event a document identified as a potential duplicate is an attachment to a parent document, hash values must be identical for the parent-plus-attachment for the documents to be considered duplicate documents. If not, any such family must be produced without deduplication of any family member. The parties will identify additional custodians who had a copy of the produced document in a metadata field associated with the produced document. The parties will produce updates to this metadata field as necessary, if it becomes outdated with subsequent productions.

F. Bates Numbering and Other Unique Identifiers. For files produced as Black and White Group IV TIFF and Medium Quality Color JPEG images, each page of a produced document must have a legible, unique page identifier ("Bates Number") electronically endorsed "burned" onto the TIFF or JPEG image in such a manner that information from the source document is not obliterated, concealed, or interfered with. There shall be no other legend or stamp placed on the document image unless a document qualifies for confidential treatment pursuant to the terms of a

Protective Order entered by this Court in this litigation, or has been redacted. In the case of Confidential Information, as defined in a Protective Order, or redacted materials a designation must be endorsed "burned" onto the document's image at a location that does not obliterate or obscure any information from the source document. Any party producing ESI in native data format under Section III.B, shall produce a slip sheet in Black and White Group IV TIFF that is endorsed with the Bates number, any applicable confidentiality stamping, and the reference to the location of the native file.

Any party producing ESI for structured data as provided in Section III.J shall employ one of the following methods for purposes of identification: (1) the ESI shall be placed in a Logical Evidence Container, e.g. a folder that is Bates numbered; or (2) the storage device (i.e., CD, USB, hard drive) containing such files shall be Bates numbered. For (1) and (2), a spreadsheet shall also be contemporaneously produced providing a Bates number and confidentiality designation, if any, corresponding to the hash value of the document.

No party may attach to any pleading or any correspondence addressed to the Court, Special Master, or any adverse or third party, or submit as an exhibit at a deposition or any other judicial proceeding, a copy of any native format document produced by any party without ensuring that the corresponding Bates number and confidentiality legend, as designated by the producing party, appears on the document.

G. Production Media. Documents shall be produced on CD-ROM, DVD, external hard drive (with standard PC compatible interface), .ftp site, or such other readily accessible computer or electronic media as the parties may hereafter agree upon (the "Production Media"). Each item of Production Media shall include: (1) the type of materials on the media (e.g., "Images," "OCR Text," "Native Files," etc.), (2) the production date, and (3) the Bates number range of the materials contained on such Production Media item. The producing party shall accompany all document

productions with a transmittal cover letter identifying by Bates number the custodial files from which the documents were produced.

H. Metadata/ Production Data. The parties agree that metadata will be produced in connection with the production of ESI in both native and static image formats. The appropriate Load/Unitization file as detailed in Section III.D above will contain the Metadata fields listed below, associated with each electronic document (or their equivalents), to the extent the fields exist as electronic Metadata associated with the original electronic documents or are created as part of the electronic data discovery process. The below list of fields does not create any obligation to create or manually code fields that are not automatically generated by the processing of the ESI, or that do not exist as part of the original Metadata of the document; provided, however, the producing party must populate the SOURCE field for all produced ESI, as well as paper Documents converted to electronic form, regardless of whether these fields would be generated during typical processing of such documents. The following list identifies the metadata fields that will be produced (to the extent available):

- Production number (including the document start and document end numbers in separate fields). This should use the standard Bates number in accordance with those used in previous productions.
- Application Used to View/Access
- BeginAttach
- EndAttach
- BeginParent
- EndParent
- Title (for E-docs)
- Subject (for emails)
- Sent/Date and Time (for emails only)

- Last Modified Date and Time; Created Date and Time (for E-docs)
- App Last Modified Date and Time; App Created Date and Time (for E-docs)
- Received Date and Time (for emails only)
- Author
- Recipients
- cc:
- bcc:
- Source (producing entity name)
- Custodian
- Hash Value
- Page Count
- Original File Name
- Doc extension
- NativeLink
- Production Volume Name
- Accessed Date & Time
- Last Print Date
- DedupCustodians (Field to identify additional custodians who had an ESI copy of the produced document, in list form separated by commas)
- DedupIDs (Field to contain DOCIDS of Duplicate ESI documents in list form separated by commas)

When a metadata field includes a date, the date shall be provided in the following format: mm/dd/yyyy HH:mm:ssZ.

Notwithstanding the foregoing, the parties will meet and confer in good faith as necessary prior to the production of documents, with technical experts as needed, to clarify or resolve any

issues (e.g., definitions of metadata fields, inconsistencies, and burden) concerning the production of metadata.

I. Attachments. Email attachments must be mapped to their parent by the Document or Production number. BeginAttach and EndAttach fields must be populated for parent documents. The BeginParent and EndParent fields must be populated for attachment documents.

J. Structured Data. To the extent a response to discovery requires production of discoverable electronic information contained in a database, in lieu of producing the database, the parties may meet and confer, with an understanding of which fields are relevant, to attempt to agree upon the sets of data or fields to be included and generate a report in a reasonably usable and exportable electronic file (e.g., Excel or CSV format) for review by the requesting party or counsel. Upon review of the report(s), the requesting party may make reasonable requests for additional information to explain the database schema, codes, abbreviations, and different report formats or to request specific data from identified fields. The parties reserve all rights to object, including but not limited to objections for relevance, undue burden, and/ or inaccessibility.

K. Prior Production. To the extent a response to discovery requires a party to provide a production set from a prior litigation/investigation, including but not limited to *Lannett Company, Inc. v Celgene Corporation*, No. 08-3920 (E.D. Pa. filed Aug. 15, 2009) and *Celgene Corporation v. Natco Pharma Ltd.*, No. 10-5197 (D.N.J. filed October 8, 2010) litigations, such party will produce the production set as it was produced in the prior litigation/investigation, with whatever metadata fields were produced in that litigation and no others. Similarly, materials provided that were previously submitted as part of a production to the Federal Trade Commission or state Attorney General will be produced as it was produced to those entities, with whatever metadata fields were produced in those submissions and no others.

L. Non-responsive Attachments and Non-responsive Redactions. The parties have not yet reached agreement regarding (a) the production or withholding of non-responsive

attachments to responsive parent documents, and (b) the redaction of non-responsive portions of otherwise responsive documents. On or before [DATE], the parties will submit a joint proposal or separate proposals regarding the handling of these issues.

IV. OBJECTIONS TO ESI PRODUCTION

A. For files produced as Black and White Group IV TIFF or Medium Quality Color JPEG images, documents that present imaging or form production problems shall be promptly identified and disclosed to the requesting party; the producing party will take reasonable steps to resolve the problem. If it is not resolved within ten (10) business days, the parties shall then meet and confer to attempt to resolve the problems.

B. If either party objects to producing the requested ESI on the grounds that such information is not reasonably accessible because of undue burden or cost, or because production in the requested format is asserted to be not reasonably accessible because of undue burden or cost, the party, at or before the time the production is due under the Federal Rules of Civil Procedure or the Case Management Order, shall describe the nature of the objection with reasonable particularity and indicate whether the producing party is willing to offer an alternative. The parties will promptly meet and confer in an attempt to resolve the objections if necessary.

C. If in-house or outside counsel for the producing party learns that responsive ESI that once existed was lost, destroyed, or is no longer retrievable as a result of acts or circumstances not occurring in the ordinary course of business or not occurring in accordance with the party's document retention policies, the producing party shall explain where and when the ESI was last retrievable in its original format, and disclose the circumstances surrounding the change in status of that ESI, and whether any backup or copy of such original ESI exists, together with the location and the custodian thereof.

V. DESIGNATED ESI LIAISON

Each party shall designate an individual(s) to act as e-discovery liaison(s) for purposes of meeting, conferring, and attending court hearings on the subject ("Designated ESI Liaison"). The Designated ESI Liaison must:

(a) be prepared to participate in e-discovery discussions and dispute resolution;

(b) be knowledgeable about the party's e-discovery efforts;

(c) be, or have reasonable access to those who are, familiar with the party's electronic systems and capabilities in order to explain those systems and answer relevant questions; and

(d) be, or have reasonable access to those who are, knowledgeable about the technical aspects of e-discovery, including electronic document storage, organization, and format issues, and relevant information retrieval technology, including search methodology.

For good cause shown, it is so ordered.

Dated this _____ day of _____, 2014.

_____

HONORABLE Michael A. Hammer, U.S.M.J.